TRIANGLE INSIGHTS GROUP by Valerís

IRA Policy Update:

CMS Negotiations Accelerate the Market Shift Toward Orphan Drugs

Triangle Insights Group Blog: Opportunities and Risks in CMS Drug Price Negotiation

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As the Inflation Reduction Act (IRA) continues to upset the pharmaceutical landscape, manufacturers are constantly monitoring policy changes and analyzing trends to try and make sense of the current market. Recent policy dynamics surrounding drug negotiations by the Centers for Medicare & Medicaid Services (CMS) reveal some key wins, losses, and strategic pivot opportunities for manufacturers going forward.

Therapeutic Area Expansion and Aggressive Pricing

The first round of negotiated prices for the 10 drugs selected by CMS for initial price applicability year (IPAY) 2026 included some of the most commonly used medications in the country, and following publication of the negotiated prices for the next 15 drugs (IPAY 2027), distinct trends are emerging regarding the negotiated prices themselves.

When comparing CMS's Maximum Fair Price (MFP) for the first and second round of negotiated drugs to the drugs' estimated Part D rebates, it is clear that the absolute delta is higher in IPAY 2027 than in IPAY 2026. The government in the past year has shown more aggressive demands in its price negotiations, and it will be important for manufacturers to consider the influence of indication and therapy area on negotiated price expectations for future IPAY years.

Manufacturers of many mainstream drugs should prepare for aggressive pricing pressure and a loss of revenue potential late in a drug's lifecycle, as well as near-term competitive impacts within their market basket.

Trending Success for the Rare Disease Space

However, aggressive negotiations by CMS have been counterbalanced by increased protections for therapeutic areas including orphan indications and rare diseases.

Previously, under the IRA, an orphan drug was only protected from CMS negotiation for its first approved orphan condition. If it received approval for any additional condition, orphan or not, the drug would then be subject to negotiation 9 to 13 years (for small molecule or biologic drugs, respectively) after its first FDA approval. However, recent revised policy has affected these protections and reshaped avenues for drug innovation.

The Advantage of the Orphan Market

The Orphan Cures Act creates a path for manufacturers to be approved in as many orphan conditions as they are able to gain FDA approval. As long as the drug is never approved in a non-orphan condition, it continues to be protected from negotiation down the line with CMS.

This enables a large strategic advantage for manufacturers developing drugs with broadly applicable mechanisms of action. In totality, a drug's addressable population might be well over orphan status across several orphan indications, but the manufacturer can still be protected from CMS price negotiations.

The pharmaceutical market has already been steadily shifting toward rare and orphan diseases, and this current policy dynamic is expected to continue accelerating that change. With mainstream drugs facing increasingly aggressive federal pricing negotiations, the protection offered by multi-orphan indication status bolsters the rare disease development path for long-term life cycle pricing potential.

Further, while models like Most Favored Nation (MFN) pricing and Direct-to-Patient (DTP) distribution serve to exacerbate pricing pressures for many CMS-negotiated and competitive drugs, orphan indications continue to be better protected from the influence of these policies given their higher net prices and often US market-focused value propositions. Manufacturers must prepare for pricing positioning trends across these policies as well, which will be discussed in upcoming blog posts.

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